DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4142

February 24, 2005

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 05 – 09

Kirk E. Hahn, DVM
Cattlesmyth Veterinary Service, LLC
9635 Hoffman Road
Coleman, Wisconsin 54112

Dear Dr. Hahn:

On October 26 and November 2, 2004, an investigator from the Food and Drug Administration (FDA) conducted an investigation involving the use of drugs in your veterinary practice. That investigation revealed that you caused animal drugs to be unsafe under Section 512(a) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 360b(a)] and adulterated within the meaning of Section 501(a)(5) of the Act [21 U.S.C. 351(a)(5)] because the drugs were used in a manner that did not conform with their approved uses or the regulations for Extralabel Drug Use in Animals, Title 21, Code of Federal Regulations, Part 530 (21 CFR 530).

The investigation documented that you compounded and prescribed for extralabel use a product ("K LMT") intended for intramammary infusion to treat mastitis in dairy cows. The product contained a combination of sulfamethoxazole, trimethoprim, gentamicin sulfate, LS-50 (lincomycin and spectinomycin), dexamethasone, and, on at least one occasion, dimethyl sulfioxide. The extralabel use of approved veterinary or human drugs in animals is permitted only if it complies with Section 512(a)(4) and Section 512(a)(5) of the Act [21 U.S.C. 360b(a)(4) and 21 U.S.C. 360b(a)(5)] and 21 CFR 530. Our investigation found that you failed to comply with 21 CFR 530 in that:

1. Your compounding and prescribing of sulfamethoxazole in combination with other drugs for extralabel treatment of mastitis in lactating dairy cows failed to comply with the requirements in 21 CFR 530.

Sulfmethoxazole is prohibited for extralabel use in lactating dairy cattle per 21 CFR 530.41(a)(9).

2. Your failure to provide legible labeling does not assure the safe and proper use of the product as required by 21 CFR 530.12. The labeling lacked information required under 21 CFR 530.12, such as the established name of each active ingredient (you omitted trimethoprim), and directions for use that includes identification of the cattle being treated with the drug, the dosage, frequency, route of administration, and duration of therapy. Furthermore, the label for "K LMT" was not entirely legible, especially for what appears to be the specified withdrawal for milk, which is required to be on the label. Thus, you failed to meet the requirement of 21 CFR 530.12 that the drug bear or be accompanied by labeling information adequate to assure the safe and proper use of the product.

3. You failed to record and maintain records of extralabel use required by 21 CFR 530.5.

We also note that, prior to prescribing or dispensing an animal or human drug for extralabel use in food-producing animals, you must establish a substantially extended withdrawal period, supported by appropriate scientific information, as required by 21 CFR 530.20(a)(2)(ii). "K LMT" has a labeled withdrawal time of 21 days for meat, but you were unable to support this withdrawal time.

Because you failed to comply with the requirements of 21 CFR 530 in compounding, prescribing, and dispensing animal drugs, your clients used new animal drugs in an unapproved manner without meeting the requirements for extralabel use set forth in Section 512(a)(4)(A) of the Act [21 U.S.C. 360b(a)(4)(A)] and 21 CFR 530, thereby rendering the drugs unsafe under Section 512 of the Act (21 U.S.C. 360b) and adulterated under Section 501(a)(5) of the Act [21 U.S.C. 360b(a)(5)].

It is not necessary for you to personally ship an adulterated drug in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of drugs that were sold in interstate commerce is sufficient to hold you responsible for a violation of the Act. The above is not intended to be an all-inclusive list of violations. As a licensed veterinarian, you are responsible for complying with the requirements of the Act, including the extralabel use regulations promulgated under the Act. You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

We have enclosed a copy of 21 CFR 530 for your reference. We strongly suggest that you review 21 CFR 530 and become familiar with all of its requirements so that you can prevent future violations of the Act.

We acknowledge your fax dated November 5, 2004. In the fax, you described the measures you had taken, and intended to take for collecting unused "K LMT" from clients to whom you had prescribed the drug. A copy of the fax is enclosed. In your response to this Warning Letter, please provide an update on the status of the corrective actions described in your fax, and state your plans for correcting the violations noted in this Warning Letter.

You should notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Please include copies of any available documentation demonstrating that your corrections have been made.

Your reply should be directed to Compliance Officer Brian D. Garthwaite, Ph.D. at the address indicated on the letterhead.

Sincerely,

W. Charles Becoat
Director
Minneapolis District

BDG/ccl

Enclosure: 21 CFR 530
Fax, 11/5/04